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Patient Inducements: Law and Limits

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Although often well-intentioned, offering free or discounted items or services to patients (*e.g.*, gifts, rewards, writing off copays, free screening exams, free supplies, *etc.*) may violate federal and state laws governing improper inducements, especially if the patient is a federal program beneficiary. The government is concerned that offering or rewarding such inducements to patients may result in overutilization, biased decisions concerning care, and increased costs to the Medicare, Medicaid, or other government programs. Penalties for illegal inducements may include administrative, civil, and criminal penalties; repayment to government programs; and exclusion from federal programs. Increasingly, private payors are also challenging such inducements. It is imperative that healthcare providers and their staff understand the applicable laws and limits.

I. Applicable Laws.

1. **Anti-Kickback Statute ("AKS").** The federal AKS prohibits anyone from knowingly and willfully soliciting, offering, receiving, or paying any form of remuneration to induce referrals for any items or services for which payment may be made by any federal healthcare program (*e.g.*, Medicare, Medicaid, *etc*.) unless the transaction is structured to fit within a regulatory exception. (42 U.S.C. § 1320a-7b(b)). The statute has been interpreted to cover any arrangement in which “one purpose” of the remuneration is to induce referrals for or receipt of federal program business. (*United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985)). An AKS violation is a felony punishable by up to 10 years in prison, a $100,000 criminal penalty, a $100,000+[i] civil penalty, treble damages, and exclusion from participating in the Medicare or Medicaid programs. (42 U.S.C. §§ 1320a-7 and 1320a-7b(b)(2)(B); 42 C.F.R. §§ 1003.300 and 1003.310; 45 C.F.R. § 102.3). An AKS violation is likely also a violation of the federal False Claims Act (42 U.S.C. § 1320a-7b(g); 31 U.S.C. § 3729), which exposes defendants to mandatory self-reports and repayments, additional civil penalties of $11,000+ to $22,000+ per claim, treble damages, private *qui tam* lawsuits, and costs of suit. (31 U.S.C. §§ 3729 and 3730; 42 U.S.C. §§ 1320a-7a and 1320a-7k(d); 28 C.F.R. §§ 85.5 and 1003.200(a) and (b)(k)).

2. **Eliminating Kickbacks in Recovery Act ("EKRA").** EKRA was enacted in response to the opioid epidemic. It parallels the AKS and prohibits offering, soliciting, paying, or receiving any remuneration to induce or reward referrals to or use of any

laboratory, clinical treatment facility, or recovery home. (18 U.S.C. § 220(a)). "Clinical treatment facilities" and "recovery homes" are generally limited to such facilities that treat or care for substance use disorders. (*Id*. at § 220(e)). However, "laboratory" is defined broadly to include any facility providing lab services whether or not related to substance use disorder. (*Id*., incorporating definition of "laboratory" at 42 U.S.C. § 263a(a)). Accordingly, any provider or facility offering lab services must beware EKRA. EKRA violations are felonies and subject the defendant to fines of up to $200,000 and up to 10 years in prison. (*Id*. at § 220(a)). Unlike the federal AKS, EKRA is not limited to referrals for government health care programs; it also applies to private pay situations. Accordingly, entities offering any remuneration to induce or reward patients for lab services must carefully review the arrangement to ensure compliance with EKRA in addition to the other statutes referenced below.

3. **Civil Monetary Penalties Law ("CMPL").** The federal CMPL prohibits, among other things, offering or providing inducements to a Medicare or Medicaid beneficiary that are likely to influence the beneficiary to order or receive items or services payable by federal healthcare programs from a particular provider, practitioner or supplier. (42 U.S.C. § 1320a-7a(a)(5); 42 C.F.R. § 1003.100(a)). "Remuneration" is defined to include the "transfers of items or services for free or for other than fair market value." (42 U.S.C. § 1320a-7a(i)(6)).

> The "inducement" element of the offense is met by any offer of valuable (*i.e.*, not inexpensive) goods and services as part of a marketing or promotional activity, regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as "word of mouth" promotion by practitioners or patient support groups. In addition, the OIG considers the provision of free goods or services to existing customers who have an ongoing relationship with a provider likely to influence those customers' future purchases.

(OIG Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries* (8/02), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf). Violations of the CMPL may result in administrative penalties ranging from $5,000+ to $100,000+ per violation depending on the conduct involved. (42 U.S.C. § 1320a-7a; 42 C.F.R. part 1003; 45 C.F.R. § 102.3).

4. **Ethics in Patient Referrals Act ("Stark").** If the patient happens to be a referring physician or the family member of a referring physician, offering free or discounted items or services or other inducements (*e.g.*, professional courtesies) may also implicate the federal Stark law. Stark generally prohibits physicians from referring certain designated health services payable by Medicare or Medicaid to an entity with which the physician, or a member of the physician's family, has a financial relationship unless the relationship is structured to fit within a regulatory safe harbor. (42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a)). Gifts, discounted items or services, and other inducements likely create a financial relationship that would trigger Stark. (42 U.S.C. § 1395nn(a)(2); 42 C.F.R. § 411.354(a)). As with AKS violations, Stark violations may result in repayment obligations; civil and administrative penalties; and False Claims Act liability. (42 U.S.C. § 1395nn(g); 42 C.F.R. §§ 1003.300 and 1003.310; 45 C.F.R. § 102.3).

5. **State Fraud and Abuse Laws.** In addition to the foregoing federal statutes, healthcare providers must beware potentially relevant state laws. Like their federal counterparts, most states have anti-kickback statutes that prohibit offering inducements to patients who are covered by Medicaid or other government healthcare programs. Some state anti-kickback statutes are broader and extend to private payors as well as government payment programs. State licensing acts often prohibit physicians and other healthcare providers from offering rebates, splitting fees, or otherwise offering kickbacks in exchange for services. Depending on the statutes, government regulators and/or private parties may try to extend those prohibitions to free or discounted items or services provided to patients, especially when the program or payments tend to induce the patient to order or receive potentially unnecessary or expensive services.

II. Applying the AKS and CMPL.

Because EKRA is limited to providers of lab services and certain substance use disorder facilities, Stark is limited to relationships with physicians or their family members, and because state laws vary, this article will focus on the AKS and CMPL, but healthcare professionals must keep EKRA, Stark and their state laws in mind and their organizations in compliance with those laws in addition to the AKS and CMPL.

The Office of Inspector General (OIG) has repeatedly confirmed that offering free or discounted items or services to government program patients potentially implicates the AKS and/or CMPL unless the program is structured to fit within a statutory or regulatory exception or certain safeguards are implemented to minimize program fraud and abuse. (*See*, *e.g.*, OIG Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries* (8/02)). Nevertheless, HHS and/or the OIG have affirmed the following safe harbors or situations in which providing free or discounted items or services would pose a relatively low risk under the statutes. In considering the potential safe harbors, healthcare providers must evaluate the AKS and CMPL separately: compliance with one does not necessarily ensure compliance with the other. The CMPL incorporates the regulatory safe harbors under the AKS (*see* 42 C.F.R. § 1003.110, definition of remuneration), but the reverse is not true: "beneficiary inducements CMP exceptions do not provide protection under the anti-kickback statute." (81 Fed. Reg. 88398).

1. **Item or Service Does Not Induce Referrals or Influence the Receipt of Care.** The AKS and CMPL are not violated so long as there is no improper intent or knowledge that the free item or service would induce referrals for or receipt of items or services payable by federal healthcare programs. Specifically, the AKS only applies if "one purpose" of the free item or service is to induce referrals for such items or services. *(Kats*, 871 F.2d 105; *Greber*, 760 F.2d 68). Similarly, the CMPL is violated only if the provider knows or should know that the remuneration is likely to influence a patient to receive such items from a particular provider. (*See* 81 Fed. Reg. 88394-95). So long as there is no such improper intent or influence, then the statutes are not violated. The OIG gave the following example under the CMPL:

> [the CMPL] only prohibits incentives that are likely to influence a beneficiary's choice of a provider for particular services. Such influence is only possible if the beneficiary knows about the incentive before making his or her choice. Thus, incentives that are not advertised or otherwise disclosed to a beneficiary before the beneficiary selects a provider for services do not come within the statutory proscription, and therefore need not qualify under any of the [CMPL] exceptions.... For example, discounted CPR courses or home visits offered to women who have delivered a child at a particular hospital are

> not prohibited ... if the availability of the discounted CPR course or home visits is not made known to the mother until after she enters the hospital to deliver her child.

(65 Fed. Reg. 24409). As noted above, however, providers must remember that "the provision of free goods or services to existing customers who have an ongoing relationship with a provider [are] likely to influence those customers' future purchases" and, therefore, such items may implicate the AKS if not the CMPL. (OIG, *Offering Gifts and Other Inducements to Beneficiaries*).

2. **Item or Service of Nominal Value.** The OIG has interpreted the CMPL to allow items or services of "nominal value," which the OIG interprets as in-kind items or services valued at no more than $15 per item or $75 in the aggregate per patient per year. (OIG, *Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries* (12/7/16), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf; *see also* 81 Fed. Reg. 88394). In its 2020 commentary, the OIG clarified that the $15/$75 guidance only applies to in-kind items or services, not cash or cash equivalents such as debit cards or gift cards that can be used for general purposes. (85 F.R. 77791).

   Importantly, the OIG has confirmed that its $15/$75 guidance "applies only with respect to the Beneficiary Inducements CMP and not the Federal anti-kickback statute." (85 F.R. 77791). While the OIG has not published a similar bright-line rule for the AKS, it has indicated that items or services of "nominal value" will not trigger the AKS. (*See*, *e.g.*, OIG *Special Fraud Alerts* dated 2/19/94, available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html). It is reasonable to assume that in-kind items or services that fit within the $15/$75 limit likely pose a low risk under the AKS, but there are no guarantees. (*See* 85 F.R. 77791).

3. **Demonstrated Financial Need.** As a general rule, the AKS and CMPL do not prohibit a provider from discounting or otherwise offering free items or services to patients who cannot afford to pay their bills. (OIG, *Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills* (2/2/04), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf). The CMPL regulations specifically except from the definition of "remuneration":

   > The offer or transfer of items or services for free or less than fair market value by a person, if--

> (i) The items or services are not offered as part of any advertisement or solicitation;
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> (ii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under [Medicare or Medicaid];
>
> (iii) There is a reasonable connection between the items or services and the medical care of the individual; and
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> (iv) The person provides the items or services after determining in good faith that the individual is in financial need.

(42 C.F.R. § 1003.110). For purposes of the CMPL "financial need" exception, "items or services" do not include cash or "cash equivalents" (81 Fed. Reg. 88402), which means:

> items convertible to cash (such as a check) or that can be used like cash (such as a general purpose debit card, but not a gift card that can be redeemed only at certain stores or for a certain purpose, like a gasoline gift card).

(81 Fed. Reg. 88393 at fn.19). As for the prohibition against advertising, the OIG explained:

> this exception is intended to protect remuneration given on a case-by-case basis, when a [financial] need is identified. It is not intended to encourage patients to seek care (in contrast to the exception for remuneration that incentivizes preventive care [discussed below]).

(81 Fed. Reg. 88402). Further, the financial need exception does not protect “offers or transfers of items or services that a provider or supplier conditions on the patient's use of other services that would be reimbursed by Medicare or a State health care program.” (*Id*.). For example, “[p]rograms that offer lodging or transportation that is

conditioned on receiving a particular service are 'tied' to the particular service and would not be protected under this exception." (*Id*.) Conversely,

> if a financially needy diabetic patient were to run out of test strips and needed an immediate supply before a refill could be authorized, the pharmacist could give the patient an extra package of test strips and not bill the patient or payor for them. This free supply is not tied to another item or service, because, in the example, the patient could not get a refill at that time. The free supply does not require the patient to purchase a prescription or anything else from the pharmacy at that time or in the future.... What this limitation prohibits is tying the purchase of a reimbursable item or service to the offer of the free item or service.

(81 Fed. Reg. 88403).

There is no similar general AKS safe harbor based on financial need, but the OIG has declared:

> **The Federal anti-kickback statute does not prohibit discounts to uninsured patients who are unable to pay their hospital bills.** However, the discounts may not be linked in any manner to the generation of business payable by a Federal health care program. Discounts offered to underinsured patients potentially raise a more significant concern under the anti-kickback statute, and hospitals should exercise care to ensure that such discounts are not tied directly or indirectly to the furnishing of items or services payable by a Federal health care program.

(OIG, *Hospital Discounts Offered to Patients Who Cannot Afford to*

Pay Their Hospital Bills at p.1). The OIG gave the following guidance concerning "financial need":

> The OIG recognizes that what constitutes a good faith determination of "financial need" may vary depending on the individual patient's circumstances and that hospitals should have flexibility to take into account relevant variables. These factors may include, for example:
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> - the local cost of living;
> - a patient's income, assets, and expenses;
> - a patient's family size; and
> - the scope and extent of a patient's medical bills.
>
> Hospitals should use a reasonable set of financial need guidelines that are based on objective criteria and appropriate for the applicable locality. The guidelines should be applied uniformly in all cases. While hospitals have flexibility in making the determination of financial need, we do not believe it is appropriate to apply inflated income guidelines that result in waivers for beneficiaries who are not in genuine financial need. Hospitals should consider that the financial status of a patient may change over time and should recheck a patient's eligibility at reasonable intervals sufficient to ensure that the patient remains in financial need.... Hospitals should take reasonable measures to document their determinations of Medicare beneficiaries' financial need. We are aware that in some situations patients may be reluctant or unable to provide documentation of their financial status. In those cases, hospitals

> may be able to use other reasonable methods for determining financial need, including, for example, documented patient interviews or questionnaires.

(*Id.* at p.4; *see also* 81 Fed. Reg. 88405).

4. **Waivers of Co-Payments or Cost Sharing Amounts.** The CMPL expressly defines "remuneration" to include "the waiver of copayment, coinsurance and deductible amounts (or any part thereof)," but it excepts

> the waiver of coinsurance and deductible amounts by a person, if the waiver is not offered as part of any advertisement or solicitation; the person does not routinely waive coinsurance or deductible amounts; and the person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection efforts.

(42 C.F.R. § 1003.110).

The AKS contains a similar exception for the waiver of copays or cost-sharing payments for certain hospital services:

> If the cost-sharing amounts are owed to a hospital for inpatient hospital services for which a Federal health care program pays under the prospective payment system, the hospital must comply with all of the following three standards:
>
> a. The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto

a Federal health care program, other payers, or individuals.

b. The hospital must offer to reduce or waive the cost-sharing amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for reimbursement is filed.

c. The hospital's offer to reduce or waive the cost-sharing amounts must not be made as part of a price reduction agreement between a hospital and a third- party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(42 C.F.R. § 1001.952(k)). Additional requirements apply to other types of providers. (*Id*.). Unless the provider can fit within the regulatory exception or otherwise prove the patient's inability to pay, the routine waiver of copays and deductibles associated with screening exams or other services almost certainly violates the AKS and/or CMPL. (*See* OIG, *Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B* (12/19/94), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html). It will also almost certainly violate private payor contracts and may result in termination of a provider's participation, breach of contract claims, and perhaps claims for insurance fraud.

5. **Preventive Care Items or Services.** The CMPL regulations define "remuneration" to also exclude:

> Incentives given to individuals to promote the delivery of

> preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include--
>
> a. Cash or instruments convertible to cash; or
> b. An incentive the value of which is disproportionally large in relationship to the value of the preventive care service (*i.e.*, either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).

(42 C.F.R. § 1003.110). The regulations further define "preventive care" as:

> any service that
>
> d. Is [i] a prenatal service or a post-natal well-baby visit or [ii] is a specific clinical service described in the current U.S. Preventive Services Task Force's Guide to Clinical Preventive Services, and
> e. Is reimbursable in whole or in part by Medicare or an applicable State health care program.

(*Id*.). Thus, “[t]he mere fact that a service involves screening, counseling or immunization will not suffice to qualify the service for the preventive care exception”; instead, only the pre- and post-natal services described in the regulation or other services identified in the *Guide to Clinical Preventive Services* fit within the exception. (65 Fed. Reg. 24408). Furthermore, the free or discounted items or services may not be “tied to the provision of other reimbursable

services" (81 Fed. Reg. 88397 n.24):

> Any tie between provision of an exempt covered preventive care service and a covered service that is not preventive would vitiate the preventive care exception and might constitute a violation of [the CMPL], the Federal anti-kickback statute, or other legal authorities.

(65 Fed. Reg. 24408). The OIG has noted that some free or discounted services may fit within the "preventive care" exceptions. For example, the OIG noted that free blood sugar screenings and cholesterol tests may fit within the exception assuming the other conditions are satisfied. (65 Fed. Reg. 24409-10).

The AKS does not contain a similar preventive care exception, but the OIG is unlikely to challenge legitimate preventive care programs so long as the free or discounted items or services are not tied to other items or services payable by federal healthcare programs:

> From an anti-kickback perspective, the chief concern is whether an arrangement to induce patients to obtain preventive care services is intended to induce other business payable by a Federal health care program. Relevant factors in making this evaluation would include, but not be limited to: the nature and scope of the preventive care services; whether the preventive care services are tied directly or indirectly to the provision of other items or services and, if so, the nature and scope of the other services; the basis on which patients are selected to receive the free or discounted services; and whether the patient is able to afford the services.

(OIG, *Supplemental Compliance Program Guidance for Hospitals*, 70 Fed. Reg. 4873 (1/31/05), available at https://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf).

6. **Items or Services Promote Access to Care.** The CMPL regulations also define "remuneration" to exclude:

> Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by--
>
> a. Being unlikely to interfere with, or skew, clinical decision making;
> b. Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
> c. Not raising patient safety or quality-of-care concerns.

(42 C.F.R. § 1003.110). The OIG commentary that accompanied the final rule clarified the scope of the exception:

First, it only applies to the provision of “items or services,” not waivers of copayments, cash or cash equivalents. (81 Fed. Reg. 88393). Thus, the exception would not apply if a physician offered a general purpose debit card to every patient who selected him for surgery. (*Id*. at 88393 and 88397).

Second, the exception only applies to items or services that “promote access to care” covered by Medicare or Medicaid, *i.e.*, items or services that improve a particular Medicare or Medicaid beneficiary's ability to obtain items or services payable by Medicare or Medicaid, but not items or services that simply reward care or incentives for complying with a treatment regimen. (81 Fed. Reg. 88393-96). The OIG provides the following helpful examples:

> We recognize that there are socioeconomic, educational, geographic, mobility, or other barriers that could prevent patients from getting necessary care (including preventive care) or from following through with a treatment plan. Our interpretation of items or

services that “promote access to care” encompasses giving patients the tools they need to remove those barriers. As we discuss below, this interpretation would not, however, incorporate the concept of rewarding patients for accessing care; the exception protects items or services that should improve a patient's ability to access care and treatment, not inducements to seek care.... For example, if a patient had a health condition for which a smoking-cessation program was a payable service, under this exception, a provider could offer free child care to the patient so that the patient could attend the program, but the provider could not give the patient movie tickets or any other reward for attending a session or series of sessions. A patient might not be able to attend the appointment without child care assistance, but the movie tickets do not improve the patient's ability to attend the appointment.... If a provider, practitioner, or supplier offered local transportation or parking reimbursement to patients for appointments for items or services payable by Medicare or a State health care program, such remuneration would improve a beneficiary's ability to access that care. Self-monitoring tools also could promote access to care. For example, a hospital might send a patient home with an inexpensive device to record data, such as weight or blood pressure, that could be transmitted to the hospital or the patient's physician. This remuneration could increase the beneficiary's ability to capture information necessary for follow-up care and to comply with the

> treatment plan...

(81 Fed. Reg. 88393).

> [S]martphone apps or low-cost fitness trackers could, depending on the circumstances, promote access to care; they could be used to track milestones and report back to the treating physician. Gift cards that relate to promoting access to care (*e.g.*, a gift card specifically for an item that would monitor the patient's health) could potentially fit into the exception as well. However, the examples structured as rewards (*e.g.*, rewards for routine exercise) would not be covered.

(*Id.* at 88395).

> [A] provider or supplier may offer educational materials (such as written materials about disease states or treatments), or informational programs (such as a program to help patients with asthma or diabetes learn more about controlling their diseases) to patients or prospective patients without implicating the beneficiary inducement CMP. However, if a provider, supplier, or other entity offered patients attending such a program an item or service (of more than nominal value), that the offeror knows or should know is likely to influence the patient to choose that provider or supplier, such remuneration would not be protected under this exception.

(*Id.* at 88396).

Third, the remuneration must pose a "low risk of harm," *i.e.*,

> the remuneration must: (1) be unlikely to interfere with, or skew, clinical decision making;

> (2) be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) not raise patient-safety or quality-of-care concerns.

(*Id.*). The OIG explained:

> For example, if a patient is discharged from the hospital with a prescription to manage newly diagnosed diabetes, cost to the Part D program might increase because of the new prescription, but overall health care costs may decrease because the patient will be managing a condition with the drug rather than having a higher chance of being re- hospitalized. Thus, we agree that the harm to be avoided is an overall increase in health care costs. However, the condition we proposed was not that the remuneration be unlikely to increase costs at all, but that it be unlikely to increase costs through overutilization or inappropriate utilization. Incentives to access a higher level of care than necessary, or to use a higher cost brand name drug instead of a lower cost generic drug would not be low risk.

(*Id.*).

In its commentary accompanying the CMPL regulations, the OIG has offered examples of how these factors may apply to common programs offered by providers:

> A sampling of remuneration that commenters suggested that we protect includes free- or reduced-cost health screenings (*e.g.*, blood pressure or fall- risk screenings); charitable dental care; education programs (*e.g.*, regarding diabetes or nutrition); post-discharge support; family

> support services; chronic condition management; education about insurance or medical leave benefits; lodging provided by a hospital the night before procedures; transportation to appointments; other services that help patients live within their own communities; discounts for copayments; and gift cards for ongoing medications....
>
> *Response*: We agree with the commenters' suggestions that free or reduced-cost health care screenings and services and discounts for drugs promote access to care and may be low risk.... We note that many forms of free or reduced cost services (*e.g.*, free screenings at a health fair or charitable dental program, post-discharge support, chronic care management) could lead the patient to seek follow-up care with the provider or supplier that offered the free service. Assuming the free screenings or health care services are not simply marketing ploys but rather identify or assist with necessary care, they could fit in the exception and be protected. Individuals and entities seeking to offer any of the listed items or services must determine, as an initial matter, whether they promote access to care (and if so, whether they are also low risk).

(81 Fed. Reg. 88396-97, emphasis added).

Again, there is no AKS exception for items or services that promote access to care. Accordingly, in evaluating AKS exposure as well as the CMPL's “risk of harm” standard, the provider should consider relevant factors identified by the OIG as referenced above, *e.g.*,

> the nature and scope of the preventive care services; whether the preventive care services are tied directly or

> indirectly to the provision of other items or services and, if so, the nature and scope of the other services; the basis on which patients are selected to receive the free or discounted services; and whether the patient is able to afford the services.

(OIG, Supplemental Compliance Program Guidance for Hospitals, 709 Fed. Reg. 4873).

7. **Value-Based Enterprises and Patient Engagement.** As amended in 2021, the AKS allows certain participants in a value-based enterprise ("VBE") to provide engagement tools or support to a patient in the target patient population of a value-based arrangement ("VBA") if certain conditions are satisfied.[1] (42 C.F.R. § 1001.952(hh)). Unlike the proposed rule, the final rule is "agnostic" as to the types of items, goods or services that may be provided: any in-kind items or services may be provided if the conditions of the safe harbor are satisfied. (85 F.R. 77788-89).

   First, the items or services must be furnished by an eligible VBE participant directly to a patient in the identified target population. (42 C.F.R. § 1001.952(hh)(2)). The safe harbor does not apply to items or services provided or funded by certain VBE participants who are excluded from the safe harbor protection, by entities who are not parties to the VBA, or to patients outside the defined target population. (*Id*. at § 1001.952(hh)(1), (4); 85 F.R. 77785-86).

   Second, the patient engagement tool or support must satisfy the following:

   a. It must be an in-kind item, good, or service, not cash or cash-equivalents. (42 C.F.R. § 1001.952(hh)(3)(i), (iii)). In its commentary, the OIG specifically noted that, while the list is not exclusive, the following items may satisfy the in-kind requirement: health technology (*e.g*., tablets for education or smartphone for communication), remote monitoring equipment (*e.g*., connected scales, blood pressure monitors, mobile apps, *etc.*), direct payment for needed services (*e.g*., utilities or broadband internet services), temporary housing, home modifications (*e.g*., grab bars, air filters, *etc*.), in-kind transportation (*e.g*., rideshare or transit ticket), voucher for certain items (*e.g*., a meal or taxi), grocery or meal delivery services, nutrition supplements, exercise or fitness equipment or programs, vehicle modifications, patient education and counseling services, gift cards that can be redeemed for only a specific permissible item (*e.g*., fuel-only gift card), *etc.* (85 F.R. 77789-96). Debit cards, rebate checks, gift cards for a “big

box" store, and other general use gift cards would not satisfy the requirement. (*Id*.). Similarly, cash or cash-equivalent rewards for healthy patient behaviors or cost-sharing waivers would not qualify. (*Id*. at 77791-93).

b. The item or service provided must have a direct connection to the coordination and management of care of a patient in the identified target patient population. (42 C.F.R. § 1001.952(hh)(3)(ii)).

> For instance, a program to provide grab bars or handrails to patients recovering from knee surgery to prevent falls at home could be properly tailored to improving health outcomes for these patients and designed to achieve safer, more effective care for this population.

(85 F.R. 77801). In contrast,

> tools and supports related to finding employment or housing related tools and supports of a routine nature, such as routine or ongoing rent or utility payments, are unlikely to meet the requirements that they be directly related to coordination and management of patient care, be recommended by the patient's licensed health care professional, and advance an enumerated goal….

(Id. at 77795).

c. The item or service must not result in medically unnecessary or inappropriate items or services reimbursable by a federal health care program. (42 C.F.R. § 1001.952(hh)(3)(iv)).

d. The item or service must be recommended by the patient's

licensed health care professional. (*Id.* at § 1001.952(hh)(3)(v)).

> [A] licensed health care professional … would be a person chosen by the patient. The term "licensed health care professional" could include, for example, the following health care professionals, assuming they are appropriately licensed by an appropriate State licensing body for each respective profession: Physicians (including doctors of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, and optometry); osteopathic practitioners; chiropractors; physician assistants; nurse practitioners; clinical nurse specialists; certified registered nurse anesthetists; physical therapists; occupational therapists; clinical psychologists; qualified speech language pathologists; qualified audiologists; and registered dietitians or nutrition professionals.

(85 F.R. 77802). It would not include "social workers, case workers, and others who may not be licensed clinicians [even though they may] play an important role in patient care…." (*Id.*).

e. The item or service must advance one or more of the following goals, each as determined by the patient's licensed health care professional: (a) adherence to a treatment regimen; (b) adherence to a drug regimen; (c) adherence to a follow-up care plan; (d) prevention or management of a disease or condition; or (e) ensure patient safety. (42 C.F.R. § 1001.952(hh)(3)(vi)).

Third, the VBE participant may not use the tool or support as a way to recruit or market patients for items or services reimbursable by government programs, *e.g.*, "an advertisement that offers to provide a free smartphone after a patient receives a service." (85 F.R. 77800; 42 C.F.R. § 1001.952(hh)(6)). The OIG distinguishes between offering basic information about a service from using the tool or service to market patients or other services. To illustrate, the OIG offered the following example:

> a VBE participant could operate a non-billable diabetes remote monitoring program to help patients manage their diabetes and coordinate their care. As part of the program, the VBE participant offers patients with diabetes a free tablet to facilitate the remote monitoring program. Should the VBE participant seek to protect the tablet under this safe harbor, it would need to satisfy the marketing and patient recruitment condition …. To illustrate the scope of this condition, we offer the following examples of educational activities that would comply with this condition. First, the VBE participant may counsel a patient with diabetes about the benefits of the non-billable remote monitoring program and explain that such program includes a free tablet to facilitate the program. Second, the VBE may explain that the tablet is used to convey information such as nutritional information, recipes, wellness tips, and appointment reminders. In these illustrative examples, the VBE participant is not using the tablet to market other reimbursable items or services or for patient recruitment.
>
> By contrast, if the VBE participant uses the tablet to send patients text messages and notifications to induce them to obtain tests, equipment, supplies, or other reimbursable

> items and services, the [marketing and recruitment] condition … would not be satisfied; the VBE participant is using the tool and support (the tablet) to market other reimbursable items and services. Similarly, if the VBE participant advertises that patients will receive a free tablet if they register for the remote monitoring program and receive services, the VBE participant is using the tool and support to recruit patients and the provision of the tablet does not qualify for safe harbor protection. It would be the same result if the VBE participant used the provision of the tablet to market other reimbursable services or recruit patients through door-to-door marketing, telephone solicitations, direct mailings, or through sales pitches masquerading as "informational" sessions.

(*Id*. at 77798).

Fourth, the item or service—or availability of the item or service—may not be determined in a manner that takes into account the type of insurance coverage of the patient. (*Id*. at § 1001.952(hh)(8)). This provision is designed to

> protect against a VBE participant targeting certain patients to receive tools and supports based on, for example, the patient's insurance or health status, resulting in targeting of particularly lucrative patients to receive tools and supports (cherry-picking) while avoiding high-cost patients (lemon-dropping).

(85 F.R. 77804). A VBE participant may define its target patient population and recipients of the specific engagement tools or supports using various factors, *e.g.*, the patient's individual needs, clinical characteristics, geographical considerations, age, income, *etc*., but may not base its decision on payor type. (*Id.*).

Fifth, the aggregate retail value of the item or service cannot exceed $500 on an annual basis, subject to an annual CPI adjustment. (42 C.F.R. § 1001.952(hh)(5)).

> The retail value of the tools and supports should be measured at the time they are provided to the patient. Specifically, for purposes of this safe harbor, the retail value is the commercial cost the patient would have incurred at the time the VBE participant provides the tool or support if the patient had procured the tool or support on the open market on their own…. The VBE participant providing the tool or support is responsible for tracking the aggregate retail value of the tools or supports that it—and only it—provides to the patient through the course of a year.

(85 F.R. 77807).

The OIG recognizes that some patients may require items or services that exceed the $500 annual cap; however, in those cases, the VBE participant would need to consider whether providing the excess item or service would violate the AKS or CMPL, whether another appropriate exception or safe harbor would apply, or whether an OIG advisory opinion should be obtained. (85 F.R. 77807).

Finally, the VBE participant must maintain records for six years and, upon HHS's request, make the records available to HHS to verify compliance. (42 C.F.R. § 1001.952(hh)(7)).

8. **Local Transportation Programs.** The AKS contains a safe harbor that allows providers to offer free or discounted local transportation programs for patients if certain conditions are satisfied. (42 C.F.R. § 1001.952(bb)). The conditions differ depending on whether the entity intends to offer such transportation on a case-by-case basis or through a shuttle service. (*Id*.). Among other things, the program: (i) must be documented in a policy and applied consistently; (ii) must not involve air, luxury or ambulance-level transportation; (iii) may not be determined in a manner related to the volume or value of federal program business; (iv) may not be marketed or advertised; (v) must be limited to established or patients; and (vi) must be restricted to certain geographic and time limits. (*Id*.).

9. **CMS-Sponsored Model Patient Incentives.** The AKS allows

participants in a CMS-sponsored model to provide patient incentives consistent with the CMS model, including specific CMS-approved programs and the Medicare shared savings program. (42 C.F.R. § 1001.952(ii)). The CMS participation documentation will specify the conditions for such patient incentives. (*Id*. at § 1001.952(4)(iii)).

10. **Not Tied to Other Care.**Based on the OIG commentary discussed above, there may be relatively minimal risk even if the hospital cannot fit within one of the foregoing regulatory exceptions so long as the provider's program promotes healthcare while minimizing the risk of fraud and abuse. Among other things, the free item or service should not be conditioned on or tied to the receipt of other items or services payable by government programs. For example, in its 2000 CMPL commentary, the OIG addressed free screening programs:

> *Comment:* One commenter ... asked whether it would be permissible for a hospital to offer free blood sugar screenings, which are not covered by Medicare, at health care fairs or as part of a National Diabetes Awareness Week campaign. The purpose of the screenings would be to increase diabetes awareness and to identify diabetic individuals who are not receiving treatment. The screenings might also identify individuals eligible for Medicare-covered diabetes self-management education programs.
>
> *Response:* Under the final rule, certain early detection tests may themselves qualify as preventive care if they are enumerated in the *Guide to Clinical Preventive Services* and covered by Medicare or an applicable State health care program. With respect to the hypothetical posed by the commenter, provision of a free non-covered screening test would not violate [the CMPL] so long as the test is not tied to the provision of other services by the hospital. Thus, for example, the screening test

> would be permissible where the hospital provides an individual who tests positive for diabetes with general information or literature and a recommendation that the individual contact his or her personal physician. If, on the other hand, as part of the screening program, the hospital makes appointments for individuals with one of its physicians, offers individuals discounts for additional covered services, or otherwise promotes its particular diabetes programs, an inference may be drawn that the free screening test was an inducement to choose the hospital as a provider of other services. Finally, we note that some early detection tests may be of such nominal value as not to come within the scope of the statutory prohibition, as discussed below.

(65 Fed. Reg. 24410, emphasis added).

In Advisory Opinion 09-11, the OIG considered a hospital's free blood-pressure screening program. The OIG stated,

> For any type of free care offered by a provider, however, regardless of whether it is preventive care as defined in the regulation, it is necessary to determine whether the free care promotes the provision of other, non- preventive care reimbursed by Medicare or Medicaid. We conclude that in the Arrangement, the free blood pressure checks are unlikely to have this effect.

(Adv. Op. 09-11 at p.5). The OIG relied on the following factors in approving the free screening program:

- The free blood pressure check offered by the hospital was not conditioned on use of any other goods or services from the hospital or any other particular practitioner or provider;
- Visitors receiving the blood pressure check were not

directed to any particular health care practitioner or provider;

- The hospital did not offer the visitor any special discounts on follow-up services; and
- Hospital staff responded to an abnormal blood pressure reading obtained during a free check by advising the visitor to see his or her own health care professional.

(*Id.*). Under these circumstances, the OIG concluded that "the Arrangement is appropriately crafted so as to avoid improper ties to the provision of other services." (*Id*.).

Although Adv. Op. 09-11 is not binding on anyone other than the parties to the agreement, the OIG's conclusion is consistent with its other statements cited above and confirms that the primary concern with free screening programs is the risk that they will tie the screening to other items or services payable by federal programs. So long as the free screening program (or other free or discounted items or services) offers a legitimate patient benefit, incorporates the safeguards identified by the OIG, and does not otherwise pose a risk of fraud and abuse, the program may pose a low risk under the CMPL and/or AKS. Of course, the analysis will depend on the particular facts of each case, including:

> the nature and scope of the preventive services; whether the preventive care services are tied directly or indirectly to the provision of other items or services and, if so, the nature and scope of the other services; the basis on which patients are selected to receive the free or discounted services; and whether the patient is able to afford the services.

(79 Fed. Reg. 4873).

III. Advisory Opinions.

As indicated above, the OIG has published a significant number of advisory opinions addressing remuneration or other inducements to patients. Although such advisory opinions are only binding on the parties, they nevertheless provide guidance for those who may wish to structure similar transactions. The OIG advisory opinions may be accessed at https://oig.hhs.gov/compliance/advisory-opinions/.

IV. Conclusion.

Offering incentives to customers may be good business in other industries, but it can result in serious consequences in the healthcare industry. Healthcare providers should beware of any marketing program that would

offer free or discounted items or services to patients as a way to generate business, especially if those patients are covered by federal healthcare programs. Before engaging in such practices, providers should review the intent and effect of the program, and determine whether the program fits within one of the regulatory exceptions or employs the OIG-approved safeguards discussed above. Failure to do so may result in significant administrative, civil and/or criminal penalties.

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[i] Many of the civil or administrative penalties are subject to periodic cost of living adjustments. (*See* 45 C.F.R. § 102.3).

[1]"VBE", "VBA", "VBE participants", "target patient population", and other relevant terms are generally defined in 42 C.F.R. § 1001.952(ee)(14) and are key to understanding the safe harbor. The safe harbor generally applies to entities who enter a structured arrangement to accomplish one or more of the following purposes as to an identified target patient population: (i) coordinating and managing care; (ii) improving the quality of care; (iii) reducing costs but not the quality of care; or (iv) transitioning from volume-based care delivery models to quality of care. (*Id*.; *see* 85 F.R. 77783). The safe harbor excludes items or services provided by certain types of VBE participants, *e.g*., most pharmaceutical, medical device, or DME manufacturers or distributors; laboratories; compound pharmacies; *etc.* (42 C.F.R. § 1001.952(hh)(1); *see* 85 F.R. 77782-83).
